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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,851	11/24/1999	KRIS E. HOLT	CIMA3.0-035	6771

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/449,851

Applicant(s)

HOLT ET AL.

Examiner

Amy E Pulliam

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-- Th MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-18 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 21.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Receipt is acknowledged of the Amendment C, received January 24, 2002.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-18, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,516,524 to Kais *et al.* (hereinafter Kais). Kais teaches a pharmaceutical composition comprising doctyl sulfosuccinate (abstract). Specifically, Kais is relied upon for the teaching that double coatings are used for taste masking. Specifically, in column 11, example 6, Kais states that the objective is to eliminate the bitter taste of the drug by applying a double coating. In column 5, lines 55-60, Kais discloses that the composition can be coated with a single coating or multiple coatings, although double coating is preferred. Further, Kais teaches that the second coating can be chosen from pH sensitive polymers. Additionally, Kais states that it is preferable for the first and second coatings to be different, although the coatings can be from the same broad group of compositions, for instance both can be pH sensitive polymers. Kais further teaches Eudragit E as an example of a pH sensitive polymer which can be used in the second coating of this invention (c 5, l 60 and c 6, l 48). Applicant does not

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claim any specific coatings, however, in the examples applicant uses Eudragit E as the taste masking layer. Therefore, Kais's disclosure of Eudragit E reads on applicant's claims to insolubility in saliva at neutral pH and solubility in saliva at acidic pH's as well as solubility in the stomach. Kais's coating must have these same characteristics, as these traits are inherent to the material. Kais further teaches that the coating materials can be between 1 and 50 weight percent of the composition (c 8, l 10-13).

Kais does not teach the specific weight percents or thicknesses of the coatings. However, it is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results.

The results must be those that accrue from the specific limitations. Absent any evidence to the contrary, it is therefore the position of the examiner that the weight percents and thicknesses claimed by applicant do not change the function of the dual coating, and therefore do not merit patentable weight.

Additionally, Kais does not teach the newly added limitation that the coated drug containing core generally has a diameter of no larger than 1500 microns. However, this is because Kais does not specify the size of the coated particles. Therefore, it is entirely possible that the coated particles of Kais are the identical size to those claimed by applicant. Furthermore, the lack of detail regarding the particle size is an indication that the particle size of the Kais formulation is a manipulatable limitation, determined as part of the process of normal optimization. Lastly, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in

order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the art would have been motivated to make a dual coated particle with applicant's limitations, based on the teachings of Kais. One of ordinary skill in the art would expect a successful taste masked formulation regardless of specific percents and thicknesses. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed January 24, 2002 have been fully considered but are not found to be persuasive.

Applicant has amended the claims to include a specific size for the coated particles. However, as addressed above in the rejection, there is no evidence that the particles disclosed in the reference are a different size than those claimed by applicant. Furthermore, absent evidence to the contrary, it is the position of the examiner that the specific particle size is a manipulatable parameter obvious to those skilled in the art.

Applicant further argues that Kais does not teach or disclose the taste masked formulation wherein the coated drug containing core has a diameter of not larger than

1500 microns. The size limitation has already been discussed. Furthermore, as stated in the above rejection, Kais specifically teaches that the objective of his composition is to eliminate the bitter taste of the drug by applying a double coating (c 11, l 27-28).

Applicant additionally argues that a person of skill in the art would not know from Kais how to obtain the claimed formulation having the advantages described in the specification. However, this argument is not persuasive, because the advantages being discussed are not present in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues that Kais teaches away from the present invention. Applicant asserts that Kais teaches a host of potential coating materials, including pH sensitive materials, and states that these coating materials can be used in any order for any layer. Applicant again asserts that in the only example of the use of a double coating system employing a pH sensitive material, the pH sensitive material is used as the inner layer. Applicant states that because there is only one example using a pH sensitive material, this is the only guidance that the reference gives in choosing among the thousands of possible combinations of coatings and layering materials. The examiner respectfully disagrees. The Kais reference specifically teaches that the preferred a double coating. Furthermore, Kais specifically gives a group of coatings which can be used as the second coating material, and this list includes pH sensitive polymers. The examiner considers this positive guidance to use a pH sensitive polymer as the second coating layer. Additionally, the reference teaches that Eudragit E is an example of a pH

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sensitive polymer. The examiner considers this positive guidance to use Eudragit E as the second coating. Although Kais does not specifically give an example using Eudragit E or another pH sensitive polymer as the second layer, it is the position of the examiner that it is clearly suggested in the teachings of the reference. Furthermore, at column 8, lines 23-25, Kais teaches a specific embodiment of the invention wherein the active is coated with a first coating, and then with a pH sensitive material. This is another example of positive, clear guidance for one of ordinary skill in the art to create a doubly coated particle, wherein the second coating is a pH sensitive material. Lastly, although Kais does give an example with Eudragit E as the inner coating, this does not eliminate the above mentioned teachings with clearly allow for pH sensitive coatings to be the outer layer, and the additional teaching that Eudragit E is an acceptable pH sensitive coating.

For the above reasons, this rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

AEP  
April 2, 2002

  
THURMAN K. PAGE  
SUPERVISORY/PATENT EXAMINER  
TECHNOLOGY CENTER 1600